JUN - 7 2001

K010862

XIV. SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
ULTRAFREE MAX STERILE LATEX POWDER-FREE SURGICAL GLOVES

Manufacturer:	Allegiance Healthcare Sdn. Bhd. Plot 87, Kampung Jawa 11900 Bayan Lepas Penang, West Malaysia
Regulatory Affairs Contact:	Erica Sethi Allegiance Healthcare Corporation 1500 Waukegan Road, MP-WM McGaw Park, IL 60085
Telephone:	(847) 785-3337
Date Summary Prepared:	3/5/01
Product Trade Name:	Ultrafree Max Sterile Latex Powder-Free Surgical Gloves
Common Name:	Surgical Glove
Classification:	Glove, Surgical
Predicate Devices:	Ultrafree Max Sterile Latex Powder-Free Surgical Gloves
Description:	Ultrafree Max Powder-Free Surgical gloves are formulated using natural rubber latex and offered sterile.
Intended Use:	Ultrafree Max Sterile Latex Powder-Free Surgical Gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination. These latex gloves contain 50 micrograms or less of total water extractable protein per gram. In addition, these gloves have been tested for use with chemotherapy drugs.

Substantial Equivalence: Ultrafree Max Sterile Latex Powder-Free Surgical Gloves with protein and chemotherapy labeling claims are substantially equivalent to Ultrafree Max Latex Powder-Free Surgical Gloves in that they provide the following characteristics:

- intended use
- size, design, packaging
- made of natural rubber latex
- physical properties
- powder-free

Summary of Testing:

Test	Result
Systemic Toxicity	Glove does not elicit any toxic reactions to acute application.
Intracutaneous Reactivity	No reactivity was observed.
Guinea Pig Maximization	Glove does not display any potential for irritation.
Ultimate Elongation & Tensile Strength	Glove meets or exceeds requirements for rubber surgical gloves per ASTM D3577-99.
Barrier Defects	Glove exceeds requirements per 21 CFR §800.20 and ASTM D3577-99.
Data/Test Method	Glove meets powder level requirements for "Powder Free" designation per ASTM D3577-99.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2001

Ms. Erica Sethi
Manager of Regulatory Affairs
Allegiance Healthcare Corporation
1500 Waukegan Road, Building WM
McGraw Park, Illinois 60085

Re: K010862
Trade/Device Name: Ultrafree Max Sterile Latex Powder-Free Surgical Gloves with Protein Labeling Claim, 50 Micrograms or Less of Total Water Extractable Protein Per Gram Plus Chemotherapy Claim
Regulation Number: 878.4460
Regulatory Class: I
Product Code: KGO
Dated: March 5, 2001
Received: March 22, 2001

Dear Ms. Sethi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to

comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Allegiance

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2460

Applicant: Allegiance Healthcare Corporation

510(k) Number (if known): K010862

Device Name: Ultrafree Max Sterile Latex Powder-Free Surgical Gloves & Protein labeling + Chemotherapy Claim.

Indications For Use: These gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination. These gloves contain 50 micrograms or less of total water extractable protein per gram. These gloves have been tested for use with chemotherapy drugs.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The Counter Use _____
(Per 21 CFR 801.109)

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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010862